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From: Grant Fairley To: Blair Lamb

Date: 5/25/2004 Time: 2:15:22 PM

Attorney Docket No. 2086.1

Confirmation No. 4572

PATENT

UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Blair Lamb

Group Art Unit: 1648

Serial No. 10/062,954

Examiner: Zacariah Lucas

Filed: January 31, 2002

For: Method of Treating Pain

Declaration Under 37 C.F.R. § 1.132

Blair Lamb states as follows:

1. I am the named inventor and applicant on the above application.
2. I reside at 5441 Randolph Crescent, Burlington, Ontario, Canada L7L 3C4.
3. I am President of 1474791 Ontario Limited having a place of business at 331 Sheddock Ave., Suite #206, Oakville, Ontario, Canada L6J 1X8.
4. My practice is in the area of General Medicine and Pain Medicine.
5. My formal education includes:
 - Bachelor of Science, University of Western Ontario, London, Ontario, Canada, 1984.
 - Degree of General Medicine, University of Western Ontario, 1988.
 - Rotating Internship at St. Joseph's Health Centre in London, Ontario, 1988-1989.
 - Canadian College of Family Practice, 1998.
 - Laser Training, Dr. Pekka Penttinen, Applications in Myofascial Dysfunction, 1994
 - IMS Training, Dr. Chann Gunn, Intramuscular Stimulation Training, 1994

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6. I have approximately 10 years of working experience in the field of pain medicine.
7. I am a member of:
 - The Ontario Medical Association, Ontario, Canada
 - The Canadian Medical Protection Association, Canada
 - The College Of Physicians and Surgeons of Ontario, Ontario, Canada
 - The Ontario Pain Physicians Association, Ontario, Canada
 - The North American Cervicogenic Headache Society
 - The Canadian College of Family Practice, Ontario, Canada
 - The Arizona Medical Board, Arizona, USA.
8. I have a number of publications in the field of pain medicine. I have provided information on chronic pain for several radio and television shows.
9. I am licensed by the College of Physicians and Surgeons of Ontario, Canada, and the Arizona Medical Board of Arizona, USA.
10. I invented the Method of Treating Pain described in the Application. The invention provides a novel method to provide sustained relaxation of the deep spinal muscles (intrinsic muscles) surrounding the vertebrae and disks to relieve pain and promote tissue healing. According to the method of the invention, the intrinsic muscles (multifidus, rotator brevis, or rotator longus) are injected with a paralyzing agent (e.g. Botox™, Myobloc™). This method provides several unexpected results as outlined below:
 - The injection maintains the muscles in a relaxed state despite their propensity for re-occurring spasm. This allows for sustained decompression of the vertebral

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segments at the injection sites which provides the unexpected result that, as the facet joints decompress, the vertebral disks decompress, and the vertebral bodies decompress for a sustained period of time, the associated tissues are able to heal.

- A further unexpected result is that the nerve roots affected by compression of disk, facet joint or vertebral body become unimpinged and can therefore heal leading to a return of normal nerve function.
- The beneficial effects associated with my method are based on treating the source of the pain by injection directly into the intrinsic muscles which then allows healing to occur.
- None of the art cited by the examiner teach or suggest direct injection into the intrinsic muscles.
- United States Patent No. 6,500,436 to Donovan discloses agents that are very specific for treating pain because they do not substantially interact and/or interfere with neurons and cells of other systems (Column 12, lines 7-10). The agents described in the patent are not administered to the intrinsic muscles and therefore would not provide the unexpected result of the healing effect.
- United States Patent No. 6,290,961 to Aoki discloses a method for relieving pain associated with muscles contractions, a method for treating conditions associated with cholinergic controlled secretions and a method of treating smooth muscle spasms. While these methods may be useful in relieving pain, they would not provide the surprising long-term benefits of tissue healing associated with paralyzing the intrinsic muscles.

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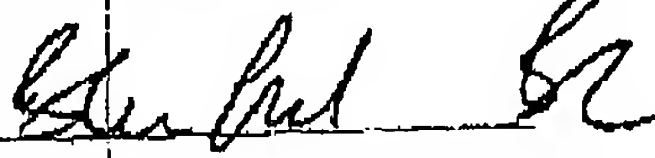
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- United States Patent No. 5,053,005 to Borodic discloses a method for modulating curvature of the spine during juvenile development. Borodic mentions injecting botulinum toxin into the paraspinal musculature using a 25 gauge tuberculin syringe. The definition of paraspinal muscles is unclear but it is clearly apparent that Borodic method could not achieve the surprising results associated with injection into the intrinsic muscles since a 25 gauge needle is neither strong enough or long enough to reach in order to administer directly to the intrinsic muscles.
- United States Patent No. 3,903,301 is directed to administering specific compounds that lack toxicity to treat muscle hyperactivity. The disclosed method could not provide the surprising benefits derived from injecting botulinum toxin directly into the intrinsic muscles.
- The method of the present invention provides a long-lasting effect that cannot be achieved by other methods that merely target pain sensors. These unexpected results associated with direct injection into the intrinsic muscles could not be achieved by injection into the larger extrinsic muscles that provide support for the spine.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued hereon.


Dr. G. Blair Lamb, MD C.C.F.P. O.P.P.A.

MAY-25-2004 15:56 FROM: SUMMA & ALLAN, P.A. 704-945-6735

TO: USPTO

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Blair Lamb *Grant Palfrey*